

## **REMARKS**

Claims 17-29 and 32-52 remain pending after amendment.

### **Rejections under 35 USC 101 and 112 (first paragraph)**

Claims 28, 29, 32-35 and 39-51 stand rejected under 35 USC 101 and 112 (first paragraph). These rejections are respectfully traversed.

In response, claim 28 was previously amended to state that the claimed method was directed to the “prophylaxis or treatment of oxidative damage *to the skin*”. As a result of the noted amendment, all independent claims are directed to “skin treatment”. As all pending claims are so limited, applicants are of the view that the outstanding rejections under 35 USC 101 and 112 (first paragraph) are without basis and should be withdrawn.

However, the Examiner again maintains the rejection based on two arguments – i.e., that (1) it is improper for the claims to recite “prophylactic” treatment, and (2) the claims are of such breadth as to embrace the treatment of “aging and wrinkling”, in connection with which the claimed invention is not supported by “either a credible asserted utility or a well established utility”.

These rejections are respectfully traversed.

As to the rejection of the Examiner on the grounds of non-enablement, the rejection is otherwise respectfully traversed.

The initial burden of establishing a prima facie case of non-enablement rests with the Examiner. In re Marzocchi, 169 USPQ 367, 369 (CCPA 1971); In re Strahilevitz, 212 USPQ 561, 563 (CCPA 1982). Indeed, “any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasons substantiating the doubts so expressed.” In re Dinh-Nguyen and Stenhagan, 181 USPQ 46, 47 (CCPA 1974).

It is only required that the specification describe the invention sufficiently for those of ordinary skill in the art to recognize that applicant invented the subject matter that is now claimed in order to comply with the requirements of the statute. In re Smyth, 178 USPQ 279, 284 (CCPA 1973). The statute merely requires that the scope of the claims bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill. In re Fisher, 166 USPQ 18, 24 (CCPA 1970). An enabling disclosure is one which allows those skilled in the art to make and use the invention without undue experimentation. In re Wands, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Notwithstanding the Examiner’s failure to meet his burden under 35 USC 112, the Examiner takes the position (without factual support) that the claimed invention lacks enabling support in the specification. The Examiner apparently believes that the specification is not enabling for a method for the prophylaxis or treatment of a

dysfunction or disease condition of the skin arising from oxidative damage such as might result from irradiation of the skin or other conditions.

Applicants have exemplified a wide variety of dysfunctions or disease conditions arising from oxidative damage at page 20 of the specification. One skilled in the art can readily practice with some predictability the claimed invention, as applicable oxidative damage conditions are well described. For the Examiner to dismiss applicants' disclosure by stating that certain of such treatments are "incredible" is without factual or legal basis.

The rejections should accordingly be withdrawn.

**Rejection under 35 USC 103(a)**

Claims 28, 29, 32-35 and 39-52 stand rejected under 35 USC 103(a) as being unpatentable over Wood et al U.S. Patent No. 4,849,346 in view of Proctor et al EP 327,263. .

The Examiner takes the position that Wood et al teaches that "oxygen radicals are known to cause a number of disruptive processes at the cellular level", concluding that "Wood et al teach the skilled artisan of the use of a spin-labeling compound to remove oxygen free radicals", and that "it would have been obvious to the skilled artisan to utilize various types of spin-labeling compounds so long as these spin-labeling compounds were pharmaceutically acceptable." Proctor is cited as teaching the "topical

administration of various types of free radical scavengers”, with the Examiner concluding that “it would have been obvious to utilize various types of compounds to act as scavengers of free radicals in order to deter the detrimental effects caused by free radicals to cell and body.” (The Examiner also makes reference to Finkelstein et al and Maillard references but does not state that they are relied upon in support of the rejection).

This rejection respectfully is traversed.

By way of review, applicants’ claims are directed to a method for the prophylaxis or treatment of a patient suffering from a dysfunction or disease condition arising from oxidative damage to the skin comprising topically administering to the patient in need thereof an effective oxidative damage-treating amount of a spin trapping compound in a pharmaceutically acceptable carrier for topical administration. In a preferred embodiment, the claims are directed to disease conditions arising from oxidative damage to the skin due to radiation, such as ultraviolet, X-ray, gamma or beta radiation. Applicants’ claimed invention is neither disclosed nor suggested by the cited prior art.

Woods is directed to a method for measuring the activity of thioredoxin reductase in mammalian cells. In the disclosed method, the cells are contacted with a hydrophobic quaternary ammonium salt comprising a stable nitroxide free radical spin label, followed by the step of measuring the rate of reduction of the free radical of the uncomplexed quaternary ammonium salt at the cell surface by electron spin resonance spectroscopy.

The rate of reduction is said to provide a measure of the thioredoxin reductase activity at the cell surface.

It is clear that Woods does not disclose or suggest the claimed method for the prophylaxis or treatment of a patient suffering from a dysfunction or disease condition arising from oxidative damage to the skin comprising topically administering to the patient in need thereof an effective oxidative damage-treating amount of a spin trapping compound in a pharmaceutically acceptable carrier for topical administration. Woods is solely directed to a method of analysis, not a method for prophylaxis or treatment of a patient. While the Examiner concludes, based on the disclosure of Woods, that "it would have been obvious to the skilled artisan to utilize various types of spin-labeling compounds so long as these spin-labeling compounds were pharmaceutically acceptable", such a conclusion is based solely on a hindsight analysis of the reference and without any suggestion regarding same. Indeed, the reference is devoid of any suggestion that a patient may be subject to prophylaxis or treatment for any reason.

The cited Proctor reference does not cure the deficiencies of Wood et al. Proctor is directed to a method for hair growth stimulation by topical administration of a nitroxide radical source, optionally together with an adjuvant selected from reducing agents, hydroxyl radical scavengers, and antioxidants to activate formation of the nitroxide radical and/or to protect the nitroxide radical from reaction with other free radicals. Proctor discloses the use of compounds such as PBN and TEMPO at page 9,

lines 19-26 which possess "spin-trapping" characteristics. However, such compounds are taught solely as hair growth stimulants, and not for use for the prophylaxis or treatment of a patient suffering from a dysfunction or disease condition arising from oxidative damage to the skin generally, and certainly not specifically for use where the oxidative damage arises from radiation such as ultraviolet radiation. See lines 11-26 of the reference in this regard which is silent on this point.

While, as noted above, the Maillard and Finkelstein references do not appear to be relied upon in support of the rejection, review of these references suggests that they are similarly irrelevant to the question at hand, apart from being directed in some way to a discussion of spin-trapping compounds.

In view of the above, the rejection is without basis and should be withdrawn.


In view of the above, the application is now believed to be in condition for allowance and an early indication of same is earnestly solicited.

A check in the amount of \$950.00 is attached for payment of the three-month extension of time requested herewith.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Very truly yours,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

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